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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,933	03/27/2007	**Galit Levin**	85189-13500	2953

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EXAMINER	
DOUKAS, MARIA E	
ART UNIT	**PAPER NUMBER**
3767	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,933	LEVIN ET AL.	
	Examiner	Art Unit	
	MARIA E. DOUKAS	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 August 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/12/2009 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 4, and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 23, 30, and 36 of copending Application No. 10/597,431. Although the conflicting claims are not identical, they are not patentably distinct from each other because in regards to application claim 1, the copending application's claim 30 anticipates this claim. In regards to copending application claim 30, the claim has the same features as application claim 1 (e.g. electrode cartridge comprising a plurality of electrodes; a main unit comprising a control unit; and an apparatus capable of generating at least one micro-channel for the intradermal or transdermal delivery of an agent). The difference in the claims is that the application claim 1 claims a cosmetic or dermatological composition and further defines the characteristics (e.g. diameter, depth) of the micro-channels. However, since copending claim 30 is generic in relation to application claim 1, it therefore anticipates the application claim 1. In regards to application claim 4, copending application claim 36 is identical and only varies in the independent claim, which is described above. In regards to application claim 14, the copending application claims 9 and 23 both teach a method for generating micro-channels in the skin of the subject that uses the same apparatus. Copending application claims 9 and 23 are generic to application claim 14, and it is therefore anticipated by the copending application claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3, 5-7, 9, 12-17, 19, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Enabling topical immunization via microporation: a novel method for pain-free and needle-free delivery of adenovirus-based vaccines" to Bramson (Bramson) in view of U.S. Patent Application Publication No. 6,302,874 to Zhang (Zhang).

In Reference to Claims 1, 14, and 24

Bramson teaches a system and method for intradermal delivery of an agent comprising: an apparatus for generating a plurality of micro-channels in the skin (Altea; p. 258, "Microporation" section) that comprises: an electrode cartridge comprising a plurality of electrodes (set of 80 μm diameter tungsten wires strapped on edge of ceramic substrate); and a main unit comprising a control unit (microprocessor control circuitry) which is adapted to apply electrical energy between two or more electrodes in the vicinity of the skin, enabling ablation of the stratum corneum (p. 259, col. 1, lines 3-9), thereby generating in the stratum corneum a plurality of micro-channels (Figure 1) having a diameter of about 10 microns to about 100 microns and a depth of about 20 microns to about 300 microns (p. 259, col. 1, lines 3-23, wherein the claimed diameter

and depth of the micro-channels falls within the range taught by the prior art, and there is therefore no structural difference between that claimed and that taught by the prior art - see MPEP §2144.05). Bramson further teaches applying a vaccine via the use of a patch to the skin after the micro-channels are created (p. 259, col. 1, "Liquid reservoir patch"). Bramson fails to teach wherein a cosmetic or dermatological composition comprising a cosmetic agent and carrier devoid of permeation enhancers is applied to the skin after the micro-channels are created. Zhang teaches producing transient pores in the skin to facilitate the transdermal delivery of a cosmetic agent composition (col. 7, lines 6-13) comprising at least one cosmetic agent and an acceptable carrier (col. 6, lines 42-53) that is devoid of permeation enhancers (col. 8, lines 33-54, whereby the permeation enhancer is described as being an optional treatment method) and further teaches wherein the composition is contained within a patch reservoir that can be attached to the skin (col. 14, lines 20-23). Zhang teaches this patch reservoir composition in order to provide a means to improve the appearance of the skin (col. 1, lines 13-17) as well as treat a variety of skin conditions (col. 5, lines 46-47).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the vaccine patch of Bramson to have the cosmetic composition as taught by Zhang instead of the vaccine and then use this patch to deliver the desired agents in order to provide a means to improve the appearance of the skin (col. 1, lines 13-17) as well as treat a variety of skin conditions (col. 5, lines 46-47). Since Bramson teaches applying a liquid reservoir patch after the micro-channels are created, one of ordinary skill in the art would be capable of modifying the type of

liquid reservoir patch that is used to have one that contains a cosmetic composition depending on the intended use of the device.

In Reference to Claim 3

Bramson in view of Zhang teaches the device of claim 1 (see rejection of claim 1 above). Bramson further teaches wherein the electrode cartridge is removable as the user removes the electrode cartridge (set of tungsten wires) after creating the micro-channels.

In Reference to Claims 5-7 and 15-17

Bramson in view of Zhang teaches the device of claims 1 and 14 (see rejection of claims 1 and 14 above). Zhang further teaches wherein the cosmetic agent is selected from the claimed group (col. 7, lines 45-48). Since claims 5 and 15 list a Markoush grouping, claims 6, 16, 7, and 17 further specify the type of xanthine and type of hydroxy acid that can be chosen from the grouping, however ascorbic acid can still be chosen as the cosmetic agent from the claim group 5, thus meeting claims 6 and 7).

In Reference to Claims 9, 12, 13, 19, 22, and 23

Bramson in view of Zhang teaches the device of claims 1 and 14 (see rejection of claims 1 and 14 above). Zhang further teaches wherein the composition further comprises at least one of the claimed components (col. 1, line 40) and is in one of the claimed forms (col. 6, lines 53-57).

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over "Enabling topical immunization via microporation: a novel method for pain-free and needle-free delivery of adenovirus-based vaccines" to Bramson (Bramson) in view of U.S. Patent Application Publication No. 6,302,874 to Zhang (Zhang).as applied to claim 1 above, and further in view of U.S. Patent Application Publication No. 2002/0010414 to Coston (Coston).

In Reference to Claim 4

Bramson in view of Zhang teaches the device of claim 1 (see rejection of claim 1 above). Bramson further teaches wherein the microporation parameters can be controlled by the user interface, but fails to explicitly teach wherein the electrical energy is of radio frequency. Coston teaches an apparatus that creates at least one micro-channel in the skin by applying electrical energy between two or more electrodes (paragraphs [0013-0015]) and teaches that the electrical energy used is of radio frequency (paragraph [0016], wherein the frequency of 30 Hz-10,000 kHz falls within the radio frequency range defined by webopedia.com to be "any frequency within the electromagnetic spectrum associated with radio wave propagation"). Although Bramson fails to explicitly teach the frequency parameter that is used to create the micro-channels, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the parameter to fall within the radio frequency range, since it has been held that where the general conditions of a claim are disclosed

in the prior art, discovering an optimum or workable range involves only routine skill in the art. Further, since the radio frequency ranges for use to create micro-channels are well known in the art, as evidenced by Coston, one with ordinary skill would be capable of using the device of Bramson within this range.

7. Claims 8, 10, 11, 18, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enabling topical immunization via microporation: a novel method for pain-free and needle-free delivery of adenovirus-based vaccines" to Bramson (Bramson) in view of U.S. Patent Application Publication No. 6,302,874 to Zhang (Zhang).as applied to claims 1, 5, 14, and 15 above, and further in view of U.S. Patent No. 6,477,410 to Henley (Henley).

In Reference to Claims 8 and 18

Bramson in view of Zhang teaches the device of claims 5 and 15 (see rejection of claims 5 and 15 above) but fails to teach wherein the cosmetic agent is hydroquinone. Henley teaches delivery of cosmetic agents to the skin that can include hydroquinone (col. 4, lines 65-66) in order to remove pigmentation from hyperpigmented areas of skin (Merriam-Webster definition). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the cosmetic agent used in the patch of Bramson in view of Zhang to be hydroquinone as taught by Henley in order to remove pigmentation from hyperpigmented areas of skin (Merriam-Webster definition). Further, it has been held to be within the general skill of a worker in the art

to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. Therefore, since the device of Bramson in view of Zhang is used for the treatment of skin conditions, and hydroquinone is well known in the art as a treatment of skin conditions, it is within the level of one of ordinary skill to use hydroquinone within the device.

In Reference to Claims 10, 11, 20, and 21

Bramson in view of Zhang teaches the device of claims 1 and 14 (see rejection of claims 1 and 14 above) but fails to teach wherein the composition further comprises an antibacterial agent. Henley teaches the delivery of antibacterial agents to the skin (col. 2, lines 9-11; col. 4, lines 49-50) in order to inhibit bacterial growth (Merriam-Webster definition). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified composition used in the patch of Bramson in view of Zhang to comprise an antibacterial agent as taught by Henley in order to inhibit bacterial growth (Merriam-Webster definition). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Response to Arguments

8. Applicant's arguments with respect to claims 1 and 3-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767